UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/142,043 | 12/01/98 | MOSSAKOWSKA D | 88362/104 |

| EXAMINER | |
|---|---|
| HAMUD, F | |
| **ART UNIT** | **PAPER NUMBER** |
| 1647 | 22 |

**DATE MAILED:** 11/07/01

026633
HELLER EHRMAN WHITE & MCAULIFFE LLP
1666 K STREET, NW
SUITE 300
WASHINGTON DC 20006

HM12/1107

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

File copy

# Advisory Action

| Application No. | Applicant(s) |
|---|---|
| 09/142,043 | MOSSAKOWSKA et al. |
| **Examiner** | **Art Unit** |
| Fozia Hamud | 1647 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED *Sep 12, 2001* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *Jul 11, 2001*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);

   (b) ☐ they raise the issue of new matter. (See NOTE below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

4. ☒ Applicant's reply has overcome the following rejection(s):
   *see attached note.*

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because:

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
   Claim(s) allowed: _____
   Claim(s) objected to: _____
   Claim(s) rejected: *37-57*

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

11. ☒ Other: Attached note

**DETAILED ACTION**

1. Receipt of Applicant's amendment and arguments in Paper No.20, filed 12 September 2001 is acknowledged.

2. Claims 37-57 are pending and are under consideration by the Examiner.

3. The following previous rejections and objections are withdrawn in light of Applicants amendments filed in Paper No.20, 09/12/01:

(I) The objection to the specification for not referencing the priority Application and for not containing an abstract.

(ii) The objection to claim 39.

(iii) The rejection of claims 37-57 under 35 U.S.C. 112, first paragraph.

(iv) The rejection of claims 37-43, 46, 48, 51-54 and 57 under 35 U.S.C. 112, second paragraph for reciting the acronym SCR3. Also the rejection of claims reciting "having" under under 35 U.S.C. 112, second paragraph is withdrawn.

***Claim rejections-Double patenting***

5a. The rejection of claims 37, 51 and 57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 10 of U.S. Patent No. 5,833,989, is maintained for reasons of record set forth in the previous office action, (Paper NO:15, mailed on 27 April 2001), page 3. Applicants argue that the claims of the instant application implicate an SCR3-derive polypeptide *containing* only 6-23 amino acids and that the claims further narrate specific size of the polypeptide. This argument was fully considered, but is not deemed persuasive, because, as was set forth in the office action of 27 April 2001, patent claims read on instant claims

37, 51 and 57, because of the open language used. Applicants amend the claims to "containing", however, *containing* is also open language which is also synonymous with "comprising" and "having". Amendment of the claims to use the closed language "consisting" would obviate this rejection.

***Claim Rejections - 35 U.S.C. § 112***

The following rejections under 35 U.S.C. 112, second paragraph are maintained for reasons record set forth in the office action mailed on Paper No:13, section 4.

6a. The reaction of claims 37-57 under 35 U.S.C. 112, second paragraph, for reciting "an SCR3-derived polypeptide...".

6b. The rejection of claims 37, 43, 48, 52-54 and 57, under 35 U.S.C. 112, second paragraph for reciting "at least a portion of sequence... " is also maintained. To overcome this rejection the following claim language is suggested:

"an isolated polypeptide that consists of a portion of SEQ ID NO:1, wherein the polypeptide consists of at least one amino acid sequence selected from the group consisting of , amino acids 6-11 of SEQ ID NO:1 and amino acids 11-20 of SEQ ID NO:1, wherein said polypeptide consists of at least 6 and no more than 23 amino acid residues."

6c. Regarding claim 39 the phrase "...comprising a chemically reactive amino acid residue at least one of the carboxyl terminus and the amino acid terminus ..." renders the claim unclear and confusing, firstly, all amino acids are chemically reactive, and thus it is unclear what do the Applicants mean by this phrase, secondly, "at least one of the carboxyl terminus...", is also unclear, a polypeptide has only

one carboxyl terminus and amino terminus, so it is confusing what is meant by "at least one of the carboxyl terminus..... Appropriate correction is required.

6d. Claims 40 and 44 recite "...wherein the chemically reactive amino acid residues derivatized or derivatizable and ... a lysine derivative", however, it is unclear with what should the chemically reactive amino acid be derivatized. Which lysine derivative? Appropriate correction is required.

6e. Claims 42 is indefinite for reciting the phrase ".....wherein the polypeptide is altered at specific positions to remove chemically reactive amino acids", which specific positions to alter? How should these be altered? What is meant by chemically reactive amino acids?. Appropriate correction is required.

6f. Claim 48 recites "...wherein polypeptide is inserted in a region of the host protein that is not essential to overall architecture of folding ...", this renders the claim vague and indefinite, Applicants should recite the specific region of the host protein wherein the polypeptide of the invention is supposed to be inserted.

***Claim rejections-35 USC § 102***

7a. The reaction of claims 37,39 and 51-57 under 35 U.S.C *§ 102*(b) as being anticipated by Fearon et al (U.S. WO 91/05047), is maintained for reasons of record set forth in the office action mailed on Paper Nos:13 and 15. Amending the claims to recite "consisting" would instead of "containing" would obviate this rejection.

***Claim Rejections - 35 USC § 103***

8a. The reaction of claims 48-50 under 35 U.S.C. 103(a) as being unpatentable over Fearon et al (WO 91/05047) in view of Capon et al (U.S. Patent 5,116,964) is mainaitined for reasons of record set forth in the office action mailed on Paper Nos:13 and 15. Amending the claims to recite "consisting" instead of "containing" would obviate this rejection.

***Conclusion***

No claim is allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday from 6:30AM to 4:00PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
06 Novemebr 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud